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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,699	04/21/2004	Karen M. Cheves	1001.1705101	5388

28075 7590 06/09/2006

CROMPTON, SEAGER & TUFTE, LLC  
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SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER
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GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

52

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/828,699	CHEVES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/26/2004</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed 3/23/2006.
2. In the reply, the Applicant noted that the IDS filed 7/26/2004 had not been considered. The IDS has now been considered.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6, 8, 12-17, 19, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Grayzel et al (6942680). In reference to independent claims 1, 12, 23 and 24, Grayzel et al discloses a medical device, comprising: an elongate shaft (54) having a proximal end, a distal end, a first lumen (col 7, lns 52-63) extending therethrough, and a second lumen (col 7, lns 52-63) extending therethrough; a balloon (44) coupled to the shaft; and one or more cutting members (46) coupled to the balloon, wherein the one or more cutting members each include a traction region (46, 48) that is configured to improve traction between the balloon and a target site, act as a means for cutting and means for gripping thereon (Figs 1-3; specification), and has an uneven traction surface (Figs 1-3; specification). Webster's defines "traction" as "the adhesive friction of a body on a surface on which it moves." Thus, it is the Examiner's

interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region.

4. In reference to claims 2, 13 (see Fig 2); claims 3, 14 (see Fig 2; 6A-C); claims 4, 15 (see Fig 3); claims 5, 16 (see Figs 6A-C); claims 6, 17 (see Fig 1-2, 8A-11); claims 8, 19 (see Figs 6A-B).

5. Claims 1, 6, 7, 12, 17, 18, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bradshaw (6450988). In reference to independent claims 1, 12, 23, and 24, Bradshaw discloses a medical device, comprising: an elongate shaft (12) having a proximal end, a distal end, a first lumen (Fig 5) extending therethrough, and a second lumen (Fig 5) extending therethrough; a balloon (16) coupled to the shaft; and one or more cutting members (30) coupled to the balloon, wherein the one or more cutting members each include a traction region (Figs 1-5) that is configured to improve traction between the balloon and a target site, act as a means for cutting and means for gripping thereon, and has an uneven traction surface (Figs 1-5). Webster's defines "traction" as "the adhesive friction of a body on a surface on which is moves." Thus, it is the Examiner's interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region.

6. In reference to claims 6-7 and 17-18 (see Figs 1 and 2).

7. Claims 1-3, 5, 12-14, 16, 23 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Lary (6306151). In reference to independent claims 1, 12, 23, and 24, Lary discloses a medical device, comprising: an elongate shaft (10) having a proximal end, a distal end, a first lumen (Fig 7) extending therethrough, and a second lumen (Fig

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7) extending therethrough; a balloon (13) coupled to the shaft; and one or more cutting members (Fig 4, 9) coupled to the balloon, wherein the one or more cutting members each include a traction region (Fig 4, 9) that is configured to improve traction between the balloon and a target site, act as a means for cutting and means for gripping thereon, and has an uneven traction surface (Fig 4, 9). Webster's defines "traction" as "the adhesive friction of a body on a surface on which is moves." Thus, it is the Examiner's interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region.

8. In reference to claims 2-3, 5, 13-14, and 16 (see Fig 9 showing saw-tooth projections having up and down undulations).

9. Claims 12, 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Vigil et al. In reference to independent claims 1, 12, 23, and 24, Vigil et al discloses a medical device, comprising: an elongate shaft (14) having a proximal end, a distal end, a first lumen (14) extending therethrough; a balloon (12) coupled to the shaft; and one or more cutting members (19) coupled to the balloon, wherein the one or more cutting members each include a traction region (Fig 6, 7) that is configured to improve traction between the balloon and a target site and act as a means for cutting and means for gripping thereon. Webster's defines "traction" as "the adhesive friction of a body on a surface on which is moves." Thus, it is the Examiner's interpretation that any region of the cutting member that contacts and engages in frictional movement with the lesion is a traction region.

10. In reference to claims 20-22, Vigil et al discloses wherein the cutting blade includes a proximally-extending connector wire (46) and a distally-extending connector wire that are both attached to the catheter shaft (Fig 4); wherein the proximally-extending connector wire and the distally-extending connector wire are connected to the catheter shaft on opposing sides of the balloon (col 4, ln 53-col 5, ln 30); wherein the cutting blades are not directly attached to the balloon (col 4, ln 53-col 5, ln 30).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al in view of Lary. Vigil et al discloses the invention substantially as claimed (see above discussion of Vigil et al) except for disclosing that the elongate shaft has a second lumen. Lary teaches that it is known to have an elongate shaft having a second lumen for the purpose of providing a guidewire lumen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the elongated as taught by Vigil et al with the second lumen as taught by Lary for the purpose of providing a guidewire lumen.

***Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/614955 or claims 1-35 of copending Application No. 10/828/572 or claims 1-20 of copending Application No. 10/447766 or claims 1-29 of copending Application No. 10/987011 or claims 1-34 of copending Application No. 10828699. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

15. Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

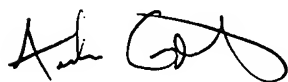
**Conclusion**

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Todd et al (5423745); Palestrant (5030201); Vigil et al (5320634); Marcadis et al (5720726); Barath (5797935); Knorig (6264633).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

